

REMARKS

In the Action mailed on June 11, 2010 the Office:

1. Acknowledged that the applicants timely filed a Request for Continued Examination (RCE) and that this RCE was entered into the record and the finality of the earlier issued final office action was removed.
2. Noted that only claims 22 and 44 are currently pending in the application, all of the other claims having been withdrawn in the RCE filed by the applicants.
3. Noted that the claims filed with the RCE were present in a small font and a faint color. Applicants wish to apologize to the Examiner for this informality and to thank the Examiner for examining the claims on the merits despite problems with their presentation. The claims presented herein bear the standard size font and coloration.
4. Rejected claims 22 and 44 under 35 U.S.C. Section 112, paragraph 2 as being indefinite. Presented herein are currently amended claims 22 and 44 which the applicants believe obviates this rejection.

Please note that the amended claim set replaces the term, "grape sperm phytosome" with the term "grape seed phytosome." The undersigned believes that the term grape sperm phytosome was a corruption of the term grape seed phytosome which likely occurred when the application was translated into the English Language. Grape seed phytosome is a natural product sometimes touted as having antioxidant properties.

5. Newly, rejected claim 22 under 35 U.S.C. Section 103(a) as being obvious over Baichwal (WO 97/26865) in view of Kim (KR 143767 B1).

Claim 22 is herein amended and the applicants respectfully request reconsideration of the rejection in view of the amendments made to claim 22 and the remarks presented herein.

Support for the amendments to claim 22 can be found throughout the application including Figures 2, 3 and 4, examples 1, 2, and 3 paragraphs 0026 to 0028 of US Pub. 2008/0206340.

The primary reference relied upon in the obviousness rejection of claim 22 is Baichwal. The Action recites that certain preferred embodiments of Baichwall's teaches that, " ... the sustained release matrix *further comprises a hydrophobic material* in an amount effective to slow the hydration of the gum without disrupting the hydrophilic matrix formed by the homolysaccharide when the formulation is exposed to fluids in an environment of use. This maybe accomplished by granulating the sustained release matrix *prior to the incorporation for*

off the medicament (thus are embedded in a botanical matrix of a botanical matrix of polysaccharide)." Action, page 4, second full paragraph (emphasis added). The only examples in Baichwal teach forming granules that include both a source of polysaccharide (in these examples locust Bean Gum) and a hydrophobic material (in these examples calcium sulfate) *before a medicament is added to the granule*. See Baichwal, Examples 1-3 pages 19-20.

In contrast to the preferred and exemplified embodiments of Baichwal the applicants' claimed invention comprises a mixture of granules one of which includes somatotropin incorporated into the matrix of a polysaccharide before the granule is formed by drying the mixture. All three of the Examples in the instant application teach mixing a bioactive ingredient with a polysaccharide and then drying the resulting mixture to form a solid which is finally milled to form the final granule. Moreover none of the granules exemplified in the instant application include the addition of a hydrophobic material. See Application, Examples 1-3, paragraphs [0026] to [0028].

As noted in the Action, Baichwal mentions that, "... the medicament may be wet-granulated *in appropriate circumstances* with one or more of the ingredients of the sustained release excipient. The remaining release excipient ingredients can simply be admixed to the resultant pre-granulated material or granulated together with the pre-granulated ingredients ...". See Action, pages 5-6 citing to Baichwal page 12, lines 3-9, emphasis added. Despite this language in Baichwal, none of the examples in Baichwal illustrate making or using such a formulation. The lack of examples and other guidance concerning 'wet granulation' of medicaments and a polysaccharide formulation illustrates that type of granule is not enabled. The only guidance provided by Baichwal in this regard is that granules in which the medicament is added before granulation may be formed in appropriate circumstance. Neither Baichwal nor any of the other references cited by the Office offer any useful guidance as to what constitutes appropriate circumstances. One of ordinary skill in the art having knowledge of Baichwal would have to engage in extensive experimentation in order to arrive at the applicants' claimed invention. In this regard, the discloser of Baichwal is an invitation to undue experimentation and does not render claim 22 obvious.

Nothing in Baichwal teaches forming a granule that does not include a hydrophobic material such as calcium sulfate. In contrast, the applicants' claimed invention does not recite the need for a hydrophobic additive. See Application, examples 1-3, paragraphs [0026] to [0028].

Moreover, as noted in the Action, Baichwal fails to disclose somatotropin. See Action, pg. 6, first full paragraph. Unlike the applicants' claimed invention, Baichwal cannot teach the advantages of associating somatotropin with a polysaccharide matrix formed by mixing somatotropin with the components of a matrix before forming the matrix. Accordingly, nothing disclosed in Baichwal would lead one of ordinary skill to add somatotropin to a mixture of galactomannan and/or a glucomannan before drying the mixture and processing the resulting dry mixture to form granules that include somatotropin associated with the lattice of a polysaccharide.

The Action cites Kim *et al.* as disclosing, a formulation for the slow release of somatotropin. Other than illustrating the somatotropin can be slowly released *in vivo*, Kim adds nothing enabling to the disclosure of Baichwal. Nor does Kim in anyway limit the amount of experimentation required to arrive at the applicants' claimed invention based on the teachings of Baichwal and Kim. Accordingly, amended claim 22 is not obvious over the art cited by the Office. And the applicants' respectfully request that amended claim 22 be entered into the record and be found in condition for allowance.

6. Rejected claims 22 and 44 under 35 U.S.C. Section 103(a) as being obvious over Baichwal (WO 97/26865) and Kim (KR 143767 B1) as applied to claim 22 in view of Shefer *et al.*, (US 2003/0195133).

Claim 44 has been amended in order to be consistent with the amendments made to claim 44. In consideration of the amendments made to the claims and submitted herewith the remarks made in regard to the patentability of amended claim 22, the applicants believe that all of the pending claims (22, 44, and 45) are now in condition for allowance.

Accordingly, the applicants respectfully request that the amended claims be entered into the record and that these claims be allowed.

In the event Applicants have overlooked the need for an extension of time, and/or the payment of additional fees, Applicants hereby petition therefore and authorize that any charges be made to Deposit Account No. 02-0385, Baker & Daniels LLP, but not to include the payment of any issue fees.

Respectfully submitted,

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